

# IMPACT OF GDUFA ON SMALL BUSINESSES

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# Small Business Representation

- Domestic FDF facility Fees stands at:
  - 2015 – \$247,717 (12.5% increase)
  - 2014 – \$220,152 (25.5% increase)
  - 2013 – \$175,389
- Minor to no impact for Multi-Billion Dollar corporations
- Major impact for small businesses

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# Impact on US Consumers

- Discouraging competition due to Barrier of Entry
- Creating Oligopoly
- Result –
  - Innovation is being hampered
  - Elimination of consumer generic drug choice
  - Drug shortages
  - Drug price inflation

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## Suggestions:

# Annual Facility/ Filing Fees

- Fees should be looked at in more details, now that we have 2 years data on hand
- Company size should be a consideration
  - Follow Other gov. agencies
- Create level playing field

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# Final Thought

- GDUFA Fees – Financial strength of a company should be taken into consideration

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# Reference

- <https://www.federalregister.gov/articles/2014/08/01/2014-18108/generic-drug-user-fee-abbreviated-new-drug-application-prior-approval-supplement-drug-master-file>
- <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM411478.pdf>

# Thank you

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